

1 CLAIMS

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3 What is claimed is:

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5 Claim 1. A method for diagnosing or monitoring  
6 multiple sclerosis (MS) in a mammal comprising:

7 obtaining a sample of body fluid from said mammal, wherein  
8 said body fluid includes blood, blood products and saliva;

9 contacting said sample with at least one protein  
10 associated with multiple sclerosis, wherein said contacting is  
11 by an enzyme-linked immunosorbent assay (ELISA);

12 determining a level of at least one autoantibody specific  
13 for said at least one protein in said sample; and,

14 comparing said level of said at least one autoantibody  
15 with statistically significant levels thereof, wherein  
16 diagnosis or monitoring of MS in said mammal is achieved.

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18 Claim 2. The method of claim 1, wherein said mammal is a  
19 human.

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21 Claim 3. The method of claim 1, wherein said protein is myelin  
22 basic protein (MBP).

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24 Claim 4. The method of claim 1, wherein said ELISA comprises  
25 the steps of:

1 mixing said sample with at least one compound effective to  
2 optimize the signal to noise ratio;

3 contacting said sample with an immunosorbent comprising  
4 said at least one protein having a high specific affinity for  
5 said at least one autoantibody; and,

6 determining an amount of said at least one autoantibody  
7 bound by said at least one protein on said immunosorbent using  
8 an antibody composition having an affinity for said at least  
9 one autoantibody and operably linked to a signal generating  
10 system.

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12 Claim 5. The method as in claim 4, wherein said signal  
13 generating system is a tetramethylbenzidine substrate.

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15 Claim 6. The method as in claim 4, wherein said at least one  
16 autoantibody is anti-MBP IgG.

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18 Claim 7. The method as in claim 6, wherein said antibody  
19 composition comprises purified anti-human IgG conjugated to  
20 horseradish peroxidase.

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22 Claim 8. The method as in claim 4, wherein said at least one  
23 autoantibody is anti-MBP IgM.

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25 Claim 9. The method as in claim 8, wherein said antibody

1 composition comprises purified anti-human IgM conjugated to  
2 horseradish peroxidase.

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4 Claim 10. The method as in claim 4, wherein said at least one  
5 autoantibody includes anti-MBP IgG and anti-MBP IgM.

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7 Claim 11. A kit for diagnosing multiple sclerosis (MS) or  
8 monitoring disease state in MS patients, comprising:

9 at least one biomolecule or an immunologically detectable  
10 fragment thereof which is upregulated in MS patients, said  
11 biomolecule having an affinity for at least one additional  
12 biomolecule whose presence is diagnostic of MS, said at least  
13 one biomolecule being immobilizable on a solid support; and,

14 at least one labeled biomolecule having a binding affinity  
15 for said at least one additional biomolecule;

16 whereby performance of at least one analysis determinative  
17 of the presence of statistically significant levels of said at  
18 least one biomolecule or an immunologically detectable fragment  
19 thereof, is carried out on a sample of body fluid and provides  
20 a means for diagnosing or monitoring disease state.

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22 Claim 12. The kit as defined in claim 11, wherein said sample  
23 of body fluid is blood, blood products, or saliva.

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25 Claim 13. The kit as defined in claim 11, wherein said at



1 is carried out on a second sample.

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3 Claim 21. The kit of claim ~~20~~, wherein said first and second  
4 samples are obtained at different time periods.  
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